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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/390,268	09/03/1999	TOM WESTBERG	F-5481	6635

7590

11/29/2002

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EXAMINER

DEAK, LESLIE R

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 11/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/390,268

Applicant(s)

WESTBERG ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 September 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7,9 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,628,908 to Kamen et al. Kamen discloses a disposable cassette for use in a dialysis system. Kamen's cassette 24 includes preformed wells and channels that serve as separate pump chambers P1 and P2, liquid paths F1 and F2, and a cyler 14 that applied positive and negative pressure to open and close the valves in the cassette (column 7, lines 52-63, column 8, lines 53-67). Further, Kamen discloses a controller that interacts with the cyler and the fluid delivery system to perform a selected fluid delivery procedure (column 5, lines 47-51).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 16-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,628,908 to Kamen et al in view of US 5,462,416 to Dennehey et al. Kamen

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discloses the apparatus as claimed, but does not disclose a set of specific fluid paths or a third pump. Dennehey discloses a fluid cassette for blood processing systems with a cassette 22 with multiple liquid paths F_N and valve stations V_N (column 6, lines 61-66). Dennehey discloses that the number and arrangement of the paths and valves may vary within the system (column 7, lines 4-8), and the cassette links with pumps in the processing system to carry out the desired procedure (column 6, lines 6-13). Further, Kamen discloses that the controller can operate first and second actuating networks 230 and 232 in tandem or independently to pump liquids between variable sources and destinations (column 19, lines 38-47). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to add an additional pumping station and variable fluid pathways as disclosed by Dennehey to the variably programmed fluid cassette disclosed by Kamen in order to have a more diverse and precisely controlled fluid transfer process within the cassette.

5. Claims 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,628,908 to Kamen et al in view of US 5,462,416 to Dennehey et al in view of US 5,795,317 to Brierton et al. The modified programmable, variable Kamen device is able to perform the blood processing process as claimed, but does not set forth the specific steps of the process. Brierton discloses and claims extracorporeal blood processing methods and apparatus that is capable of running several fluid flow procedures in order to separate the blood. In particular, Brierton discloses that his apparatus allows blood to pass through a needle assembly 30 to a cassette 110 and on to a processing module 352, where the blood is separated. The platelet stream exits the separation module

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back through the cassette and at least a portion of it is collected in assembly 80, or diverted to reservoir 150. Further, separated plasma exits the separation device through the cassette for storage in tubing 90 or reservoir 150, and red blood cells also flow from the separation device through the cassette to a reservoir. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to adapt the modified programmable, variable Kamen device to include the multiple separation modes and processes disclosed by Brierton in order to eliminate extraneous tubing in the Brierton device and to provide a more diverse and precise blood separation process.

Response to Arguments

6. In response to applicant's argument that the Kamen reference fails to disclose that the actuator may be employed to place any given pump in communication with any given flow path, the recited limitation amounts to a recitation of intended use. Claims 1, 6, and 16 contain limitations that are drawn to the operation of a controller that functions to operate the device in a given manner ("a pneumatic actuator... to apply...;" "a controller... to direct...;"). Claims 11, 25, and 35 contain limitations drawn to the operation of the system as a whole ("system being configured to place...;" "may be placed..."). A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as

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compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicant argues that Kamen discloses that the liquid flow paths are associated with specific pump chambers. However, contrary to applicant's assertion, Kamen does *not* teach nor disclose that the associations (as pointed out by applicant in column 8, lines 15-22) are exclusive. Nowhere does Kamen say that the flow paths are associated "only" with the pumps disclosed. Furthermore, applicant's recitation of the system's configuration allowing pump stations to be associated with "any" fluid flow path in the system includes those that Kamen discloses as associated with a specific pumping station. Therefore, the Kamen reference continues to anticipate applicant's claims drawn to the association between the pump stations and "any" fluid flow path.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0873.

lrd 
November 26, 2002



ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700